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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/766,403

01/27/2004

Luiz Belardinelli

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07/02/2008

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EXAMINER

CRANE, LAWRENCE E

ART UNIT

PAPER NUMBER

1623

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/766,403	<b>Applicant(s)</b> BELARDINELLI ET AL.	
	<b>Examiner</b> Lawrence E. Crane	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on April 15, 2008 (amendment).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 64-89 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 64-89 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The instant disclosure fails to include an accurate "Cross-References to Related Applications." See 37 C.F.R. §1.78 and MPEP at §201.11. Applicant is respectfully requested to amend the first paragraph of the disclosure to refer to application number 10/629,368 in place of 10/629,386, and similarly to correct one of the provisional applications to refer to Ser. No. 60/426,902 in place of 60/462,902.

The disclosure is objected to because of the following informalities:

At page 11, line 22, the term "CVC-3146" appears to include a typographical error. Did applicant intend the term to read  
-- CVT-3146 --?

Appropriate correction is required.

Claims **2-4, 9, 18 and 32-61** were previously cancelled, claims **1, 5-8, 10-17, 19-31 and 62-63** have been cancelled, no claims have been amended, the disclosure has not been amended, and new claims **64-89** have been added as per the amendment filed April 15, 2008. No additional or supplemental Information Disclosure Statements (IDSs) have been filed as of the date of this Office action.

Claims **64-89** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line **y**, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claim **64** is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **64** at lines 8-9, the term "non-toxic amount of methylboronic acid in solution" is directed to subject matter that is inconsistent with the disclosure wherein buffers at pH greater

than 9 are disclosed for “buffers” containing methylboronic acid are disclosed, suggesting that the noted claim is missing essential subject matter; e.g. a substance or substances capable of making methylboronic acid (solid) into part of a liquid buffer of the appropriate pH or pH range. A clarifying amendment, an appropriate explanation, or another appropriate action is respectfully requested.

Applicant’s arguments with respect to claims **1-63** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant’s amendment.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **64-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-11** of copending Application No. **11/253,322** in view of **Swinyard et al.** (PTO-892 ref. **R**).

In the portion of the ‘**322** application at pages 8-9, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including “buffers.” This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief

vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The ‘**322**’ reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al.** reference is a very well known in the art source of guidance concerning how to prepare a buffered pharmaceutical composition, and in the portion cited, borate buffers are provided as a specific example.

In light of the generic teaching of “buffered” CVT-3146 compositions in the ‘**322**’ application, it would have been obvious to substitute the boric acid/borate taught by **Swinyard et al.** and/or the analogous methylboronic-acid-based buffers as alternatives to the buffers taught generically by the ‘**322**’ application, in order to obtain a pH 8.5-to-pH 10 buffered composition comprising CVT-3146, a change that applicant has disclosed as improving the solubility of CVT-3146.

One having ordinary skill in the art would have been motivated to combine these references because the ‘**322**’ application teaches buffered pharmaceutical compositions and the **Swinyard et al.** reference discloses buffers and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant’s arguments with respect to claims **1-63** have been considered but are moot in view of the new grounds of rejection.

Claims **64-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-4, 6-18 and 21-30** of copending Application No. **10/629,368** in view of **Swinyard et al.** (PTO-892 ref. **R**). .

In the portion of the ‘**368** application at page 10, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including “buffers.” This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The ‘**368** reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al.** reference is a very well known in the art source of guidance concerning how to prepare a buffered pharmaceutical composition, and in the portion cited, borate buffers are provided as a specific example.

In light of the generic teaching of “buffered” CVT-3146 compositions in the ‘**368** application, it would have been obvious to substitute the boric acid/borate taught by **Swinyard et al.** and/or the analogous methylboronic-acid-based buffers as alternatives to the buffers taught generically by the ‘**368** application, in order to obtain a pH 8.5-to-pH 10 buffered composition comprising CVT-3146, a change that applicant has disclosed as improving the solubility of CVT-3146.

One having ordinary skill in the art would have been motivated to combine these references because the ‘**368** application teaches buffered pharmaceutical compositions and the **Swinyard et al.** reference discloses buffers and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant’s arguments with respect to claims **1-63** have been considered but are moot in view of the new grounds of rejection.

Claims **64-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **11, 14-27, 29-30, 34 and 36-37** of copending Application No. **11/070,768** in view of **Swinyard et al.** (PTO-892 ref. **R**). .

In the portion of the **'768** application at pages 12-13, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including "buffers." This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The **'768** reference does not specify or otherwise teach buffered compositions comprising CVT-3146 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al.** reference is a very well known in the art source of guidance concerning how to prepare a buffered pharmaceutical composition, and in the portion cited, borate buffers are provided as a specific example.

In light of the generic teaching of "buffered" CVT-3146 compositions in the **'768** application, it would have been obvious to substitute the boric acid/borate taught by **Swinyard et al.** and/or the analogous methylboronic-acid-based buffers as alternatives to the buffers taught generically by the **'768** application, in order to obtain a pH 8.5-to-pH 10 buffered composition comprising CVT-3146, a change that applicant has disclosed as improving the solubility of CVT-3146.

One having ordinary skill in the art would have been motivated to combine these references because the **'768** application teaches buffered pharmaceutical compositions and the **Swinyard et al.** reference discloses buffers and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims **1-63** have been considered but are moot in view of the new grounds of rejection.

Claims **64-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **5-8 and 10-22** of U. S. Patent **7,183,264** (PTO-892 ref. **B**) in view of **Swinyard et al.** (PTO-892 ref. **R**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods of treatment in both applications involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging, the only difference being the presence of a different buffer.

In the portion of the '**264** patent beginning at column 15, line 32, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including "buffers." This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The '**264** patent reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al.** reference is a very well known in the art source of guidance concerning how to prepare a buffered pharmaceutical composition, and in the portion cited, borate buffers are provided as a specific example.

In light of the generic teaching of "buffered" CVT-3146 compositions in the '**264** patent, it would have been obvious to substitute the boric acid/borate taught by **Swinyard et al.** and/or the analogous methylboronic-acid-based buffers as alternatives to the buffers taught generically by the '**264** patent, in order to obtain a pH 8.5-to-pH 10 buffered composition comprising CVT-3146, a change that applicant has disclosed as improving the solubility of CVT-3146.



One having ordinary skill in the art would have been motivated to combine these references because the **'264** patent teaches buffered pharmaceutical compositions and the **Swinyard et al.** reference discloses buffers and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

Applicant's arguments with respect to claims **1-63** have been considered but are moot in view of the new grounds of rejection.

Claims **64-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **10-24** of U. S. Patent **7,144,872** (PTO-1449 (#5) ref. **E5**) in view of **Swinyard et al.** (PTO-892 ref. **R**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods of treatment in both applications involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging, the only difference being the presence of a different buffer.

In the portion of the **'872** patent beginning at column 15, line 30, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including "buffers." This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The **'872** patent reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al.** reference is a very well known in the art source of guidance concerning how to prepare a buffered pharmaceutical composition, and in the portion cited, borate buffers are provided as a specific example.

In light of the generic teaching of “buffered” CVT-3146 compositions in the ‘872 patent, it would have been obvious to substitute the boric acid/borate taught by **Swinyard et al.** and/or the analogous methylboronic-acid-based buffers as alternatives to the buffers taught generically by the ‘872 patent, in order to obtain a pH 8.5-to-pH 10 buffered composition comprising CVT-3146, a change that applicant has disclosed as improving the solubility of CVT-3146.

One having ordinary skill in the art would have been motivated to combine these references because the ‘872 patent teaches buffered pharmaceutical compositions and the **Swinyard et al.** reference discloses buffers and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

Applicant’s arguments with respect to claims **1-63** have been considered but are moot in view of the new grounds of rejection.

Claims **64-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **9, 10, 11 and 16** of U. S. Patent No. **6,642,210** (PTO-1449 (#3) ref. **A15**) in view of **Swinyard et al.** (PTO-892 ref. **R**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods of treatment in both applications involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging, the only difference being the presence of a different buffer.

In the portion of the ‘**210** patent beginning at column 16, line 5, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including “buffers.” This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The ‘**210** patent reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al.** reference is a very well known in the art source of guidance concerning how to prepare a buffered pharmaceutical composition, and in the portion cited, borate buffers are provided as a specific example.

In light of the generic teaching of “buffered” CVT-3146 compositions in the ‘**210** patent, it would have been obvious to substitute the boric acid/borate taught by **Swinyard et al.** and/or the analogous methylboronic-acid-based buffers as alternatives to the buffers taught generically by the ‘**210** patent, in order to obtain a pH 8.5-to-pH 10 buffered composition comprising CVT-3146, a change that applicant has disclosed as improving the solubility of CVT-3146.

One having ordinary skill in the art would have been motivated to combine these references because the ‘**210** patent teaches buffered pharmaceutical compositions and the **Swinyard et al.** reference discloses buffers and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

Applicant’s arguments with respect to claims **1-63** have been considered but are moot in view of the new grounds of rejection.

Claims **64-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **9-13** of U. S. Patent No. **6,403,567** (PTO-1449 (#1) ref. **A13**) in view of **Swinyard et al.** (PTO-892 ref. **R**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods of treatment in both applications involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging, the only difference being the presence of a different buffer.

In the portion of the ‘567 patent beginning at column 14, line 58, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including “buffers.” This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The ‘567 patent reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al.** reference is a very well known in the art source of guidance concerning how to prepare a buffered pharmaceutical composition, and in the portion cited, borate buffers are provided as a specific example.

In light of the generic teaching of “buffered” CVT-3146 compositions in the ‘567 patent, it would have been obvious to substitute the boric acid/borate taught by **Swinyard et al.** and/or the analogous methylboronic-acid-based buffers as alternatives to the buffers taught generically by the ‘567 patent, in order to obtain a pH 8.5-to-pH 10 buffered composition comprising CVT-3146, a change that applicant has disclosed as improving the solubility of CVT-3146.

One having ordinary skill in the art would have been motivated to combine these references because the ‘567 patent teaches buffered pharmaceutical compositions and the **Swinyard et al.** reference discloses buffers and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

Applicant’s arguments with respect to claims **1-63** have been considered but are moot in view of the new grounds of rejection.

Claims **64-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **26-44** of U. S. Application No. **11/588,834**

(PTO-1449 (#5) ref. **D5**) in view of **Swinyard et al.** (PTO-892 ref. **R**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment wherein either coronary vasodilation, or increased coronary blood flow made possible by said vasodilation, is induced by administration of the identical active ingredient, CVT-3146 in the presence of a small amount of a different buffer.

In the portion of the **'834** application at page 20, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including "buffers." This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The **'834** reference does not specify or otherwise teach buffered compositions comprising CVT-3146 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al.** reference is a very well known in the art source of guidance concerning how to prepare a buffered pharmaceutical composition, and in the portion cited, borate buffers are provided as a specific example.

In light of the generic teaching of "buffered" CVT-3146 compositions in the **'834** application, it would have been obvious to substitute the boric acid/borate taught by **Swinyard et al.** and/or the analogous methylboronic-acid-based buffers as alternatives to the buffers taught generically by the **'834** application, in order to obtain a pH 8.5-to-pH 10 buffered composition comprising CVT-3146, a change that applicant has disclosed as improving the solubility of CVT-3146.

One having ordinary skill in the art would have been motivated to combine these references because the **'834** application teaches buffered pharmaceutical compositions and the **Swinyard et al.** reference discloses buffers and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims **1-63** have been considered but are moot in view of the new grounds of rejection.

Claims **64-89** of this application conflict with claims **1-11** of copending Application No. **11/253,322**, claims **1-4, 6-18 and 21-30** of copending Application No. **10/629,368**, claims **11, 14-27, 29-30, 34 and 36-37** of copending Application No. **11/070,768**, and claims **26-44** of U. S. Application No. **11/588,834**. 37 C.F.R. §1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP §822.

Applicant is respectfully requested to supply the serial numbers of any other US Patents assigned to CV Therapeutics and any other US Patent applications assigned to CV Therapeutics that claim subject matter overlapping with instant claims **64-89**.

The above Office action contains one new ground of rejection and therefore could not be made final.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < <http://pair-direct.uspto.gov> >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec  
**06/27/2008**

/Lawrence E. Crane/

Patent Examiner, Art Unit 1623

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L. E. Crane, Ph.D. Esq.  
Patent Examiner  
Technology Center 1600